

**REMARKS**

Claims 1-4 are currently pending. Claims 1 and 2 have been amended to more clearly describe the claimed invention. The amendments to the claims are supported by the specification and claims as originally filed, including for example, at pages 8-9, paragraph 27; page 13, paragraph 37; and pages 22-25, paragraph 56. No new matter is added by way of this amendment.

**I. Rejection Under 35 U.S.C. § 103(a)**

**A. U.S. Patent No. 5,965,610 to Modak et al. in view of U.S. Patent No. 5,516,510 to Beilfuss et al. and U.S. Patent No. 5,906,808 to Osborne et al.**

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,965,610 to Modak et al. (hereafter, “Modak”) in view of U.S. Patent No. 5,516,510 to Beilfuss et al. (hereafter “Beilfuss”) and U.S. Patent No. 5,906,808 to Osborne et al. (hereafter “Osborne”). The Examiner contends that Modak discloses an irritant-inactivating composition comprising an antimicrobial, such as, for example, benzalkonium chloride, triclosan or chlorhexidine digluconate, as well as zinc compounds such as zinc acetate, zinc gluconate, zinc oxide, zinc stearate and zinc salicylate. The Examiner also alleges that Beilfuss describes an antimicrobial deodorant composition comprising octoxyglycerin and an antimicrobial (e.g. chlorhexidine salt), wherein the composition is effective against gram positive and gram negative microorganisms, and further, that combining glycerin monoalkyl ethers with antimicrobial agents results in a synergistic antimicrobial effect. Finally, the Examiner states that Osborne discloses compositions (e.g., surgical scrubs) comprising antimicrobials (e.g., chlorhexidine) and an emulsifying wax, such as Polowax A-31. Thus, according to the Examiner, it would have been obvious to combine the different agents of Modak, Beilfuss and Osborne to arrive at the claimed invention.

Applicants respectfully traverse the rejection and request reconsideration. To support an assertion of obviousness, the Examiner must show that “all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more

than predictable results to one of ordinary skill in the art." M.P.E.P. § 2143. *See also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 82 (2007).

Applicants respectfully submit that the claims of the present application are not obvious over the cited references because the combined teachings of the references do not suggest or describe all elements of the claims as amended herein. The claims as amended are directed to an antimicrobial hydroalcoholic gel composition comprising a first antimicrobial agent consisting of synergistic amounts of octoxyglycerin and a quaternary ammonium compound (e.g., benzalkonium chloride), a second antimicrobial agent (e.g., chlorhexidine digluconate), and two different zinc compounds. None of Modak, Beilfuss or Osborne, considered alone or in combination, disclose or suggest an antimicrobial hydroalcoholic gel composition comprising synergistic amounts of octoxyglycerin and a quaternary ammonium compound, further comprising two different zinc salts.

First, claims 1 and 2 have been amended to recite a composition comprising a first antimicrobial agent consisting of synergistic amounts of octoxyglycerin and a quaternary ammonium compound (claim 1), and a first antimicrobial agent consisting of synergistic amounts of octoxyglycerin and benzalkonium chloride (claim 2). None of Modak, Beilfuss or Osborne considered alone or in combination, disclose an antimicrobial hydroalcoholic gel comprising synergistic amounts of octoxyglycerin and a quaternary ammonium compound (e.g., benzalkonium chloride). Assuming arguendo, and not by way of concession, that Beilfuss describes that octoxyglycerin can interact synergistically with other antimicrobial agents, none of which are specified by the reference, and that Modak discloses that benzalkonium chloride can act synergistically with parachlorometaxylenol and chlorhexidine, as alleged by the Examiner, it would still remain that none of the references suggest or describe a composition comprising amounts of octoxyglycerin and a quaternary ammonium compound that interact synergistically, as recited by the claims. Thus, the combined teaching of the cited references does not disclose all elements of the amended claims.

Additionally, the Examiner relies on Modak for the disclosure that a zinc compound may be incorporated into a composition comprising an antimicrobial agent, wherein the zinc compound prevents the antimicrobial from binding to a surface. *See*, the 5/27/09 Office Action (hereafter, "the Office Action"), at page 3. However, in contrast to the pending claims, as amended herein, which recite that the claimed antimicrobial composition is a hydroalcoholic gel

comprising two zinc compounds, Modak discloses that a gel composition comprising an irritant-inactivating agent (*i.e.*, an antimicrobial agent), includes a single zinc compound, specifically zinc gluconate, as the substance that prevents the irritant-inactivating agent from binding to a surface. *See*, Modak at Col. 7, lines 50-62. No where does Modak suggest or indicate that other zinc compounds may be used. As discussed in further detail below, Modak was unsuccessful at using other zinc compounds in a gel matrix. Thus, combining the various ingredients of the cited references does not produce an antimicrobial gel possessing all the elements of the pending claims, and as such, does not render the claims obvious.

With regard to Beilfuss and Osborne, Applicants submit that neither of the two references suggest or describe that two zinc salts can be combined together in a hydroalcoholic gel with antimicrobial agents. Beilfuss describes an antimicrobial deodorant composition comprising octoxyglycerin and an antimicrobial, while Osborne discloses compositions comprising antimicrobials and an emulsifying wax, such as Polowax A-31. Thus, combining the disclosures of Beilfuss and Osborne with that of Modak does not cure Modak's deficiency in describing all the elements of the claimed antimicrobial hydroalcoholic gel. Specifically, the combined disclosure of the cited references does not describe an antimicrobial hydroalcoholic gel comprising two different zinc salts. Therefore, Applicants' submit that the claims are not obvious over the combined teaching of Modak, Beilfuss and Osborne.

Additionally, with regard to the Examiner's contention that it would have been obvious to combine the various elements of the cited art, Applicants submit that while there are limited circumstances where an obviousness rejection may fairly be based on a contention that the invention was obvious to try, the instant rejection does not fall within those limited circumstances. As noted by the Supreme Court in *KSR v Teleflex*, 127 S.Ct. 1727, 1739 (2007), it is inappropriate to employ an obvious to try argument in situations where the outcome cannot be reasonably predicted. *See, KSR v. Teleflex*, 127 S.Ct. 1727, 1739 (2007). This distinction between predictable situations where an obvious to try argument is appropriate and unpredictable situations where an obvious to try argument is an inappropriate basis for obviousness was recently clarified further by the Federal Circuit in *In re Kubin*, 561 F.3d 1531 (Fed. Cir. 2009):

In [unpredictable] circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness. The inverse of this proposition is succinctly

encapsulated by the Supreme Court's statement in *KSR* that where a skilled artisan merely pursues "known options" from a "finite number of identified, predictable solutions," obviousness under § 103 arises.

*In re Kubin*, 561 F.3d 1531, 1359 (Fed. Cir. 2009).

In the present application, the claims are directed to a composition which exhibits antimicrobial synergy achieved by combining antimicrobially synergistic amounts of octoxyglycerin and a quaternary ammonium compound (*e.g.*, benzalkonium chloride). An artisan of ordinary skill, in view of the cited references, would have no way of predicting that octoxyglycerin and a quaternary ammonium compound would interact synergistically, as recited by the claims. At best, in view of Beilfuss' disclosure that octoxyglycerin can interact synergistically with other antimicrobial agents (none of which are disclosed by the reference), the skilled artisan would have been reduced to randomly combining octoxyglycerin with different antimicrobial agents from the vast number of antimicrobials disclosed by the cited references, and testing for a synergistic effect. Specifically, without knowledge of the instant application, in which Applicants demonstrate that octoxyglycerin and a quaternary ammonium compound interact synergistically, the skilled artisan would not have expected or predicted that the two compounds could be combined to achieve such an effect.

Furthermore, the claims as amended are not obvious over the combined teaching of Modak, Beilfuss and Osborne because an artisan of ordinary skill, in view of the cited references, would have no expectation that the elements of the different references could be successfully combined into a hydroalcoholic gel composition as described by the claims. As previously discussed, the claims are directed to a hydroalcoholic gel composition comprising two zinc salts. However, according to Modak, only one zinc salt, zinc gluconate, could be successfully incorporated into a gel matrix comprising an antimicrobial agent. *See*, Modak at Col. 7, lines 24-62. As described by Modak, numerous zinc salts were tested for use in combination with an irritant-inactivating substance (*i.e.*, an antimicrobial agent), and only zinc gluconate was able to successfully form a gel matrix when combined with the antimicrobial. *See*, Modak at Col. 7, lines 24-41. Thus, in view of Modak, a skilled artisan seeking to formulate an antimicrobial gel comprising zinc would formulate such a gel with only zinc gluconate, since, according to Modak, other zinc salts do not form a gel matrix when combined with an irritant-inactivating substance. Therefore, in view of the failure of the combined disclosure of the cited references to

describe all the elements of the claimed composition, and further, because an artisan of ordinary skill, in view of the cited references, would have no expectation of successfully combining the elements of the claimed invention, Applicants submit that the claims are not obvious over the cited prior art, and respectfully request that the rejections be withdrawn.

B. U.S. Patent No. 5,980,925 to Jampani et al. in view of U.S. Patent No. 6,040,347 to Cupferman et al. and U.S. Patent No. 5,906,808 to Osborne et al.

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,980,925 to Jampani et al. (hereafter “Jampani”) in view of U.S. Patent No. 6,040,347 to Cupferman et al. (hereafter “Cupferman”) and Osborne. The Examiner contends that Jampani describes compositions comprising antimicrobials (e.g., chlorhexidine and benzalkonium chloride), glycerin and zinc oxide. The Examiner also alleges that Cupferman discloses compositions comprising octoxyglycerin for treating acne, while Osborne discloses compositions comprising antimicrobials and an emulsifying wax, such as Polowax A-31. The Examiner contends that it would have been obvious to combine the ingredients of the cited references into a single composition as described by the claims.

Applicants respectfully submit that the claims as amended are not obvious over the cited references because the combined teaching of the references does not disclose all the elements of the amended claims. As previously discussed above, the claims as amended are directed to an antimicrobial hydroalcoholic gel composition comprising a first antimicrobial agent consisting of synergistic amounts of octoxyglycerin and a quaternary ammonium compound (e.g., benzalkonium chloride), a second antimicrobial agent (e.g., chlorhexidine digluconate), and two different zinc compounds. None of Jampani, Cupferman or Osborne, considered alone or in combination, disclose an antimicrobial hydroalcoholic gel composition comprising two different zinc compounds and synergistic amounts of octoxyglycerin and a quaternary ammonium compound.

Jampani describes a composition comprising an active ingredient (e.g., an antimicrobial) and a glycerin anchoring agent. Although the reference discloses that the active ingredient may be zinc oxide (see, Jampani at Col. 5. lines 27-38), the reference does not suggest or describe a hydroalcoholic gel comprising two different zinc compounds and an antimicrobial agent consisting of synergistic amounts of octoxyglycerin and a quaternary ammonium compound. With regard to Cupferman and Osborne, the two references describe compositions comprising

octoxyglycerin and an emulsifying wax, respectively. Neither of the two references suggest or describe compositions comprising zinc salts. Thus, combining the disclosures of Cupferman and Osborne with that of Jampani does not describe a composition comprising all the elements of the claims as amended. For this reason, the claims are not obvious over the cited references.

Additionally, Applicants note that the claims have also been amended to recite that the claimed composition comprises a first antimicrobial agent consisting of synergistic amounts of octoxyglycerin and a quaternary ammonium compound. The Examiner contends that it is known in the art that octoxyglycerin can interact synergistically with other antimicrobials, as evidenced by U.S. Patent No. 5,736,574 to Burnier et al. (*see*, the Office Action at page 9), and thus a combinatory immixture of at least one antimicrobial agent and octoxyglycerin would intrinsically manifest a synergistic antimicrobial effect.

Applicants respectfully disagree. The amended claims recite that octoxyglycerin interacts synergistically with a specific antimicrobial agent (*i.e.*, a quaternary ammonium compound, such as benzalkonium chloride), not merely any antimicrobial agent. None of Jampani, Cupferman, Osborne or Burnier suggest or describe that any amount of octoxyglycerin can interact synergistically with a quaternary ammonium compound, as recited by the claims. Thus, while an artisan of ordinary skill, for arguments sake, and not by way of concession, may have understood that octoxyglycerin can interact synergistically with some antimicrobials, such as N-Octanoylglycine as described by Burnier and as suggested by the Examiner, without the teaching of the instant application, the artisan would have no expectation that octoxyglycerin could interact synergistically with a quaternary ammonium compound.

Furthermore, Applicants note that Cupferman is directed to antimicrobial agents that can be used in a topical composition as an alternative to benzalkonium chloride in order to avoid purported disadvantages of benzalkonium chloride. Thus, in addition to lacking an expectation that octoxyglycerin and a quaternary ammonium compound can interact synergistically, the skilled artisan, in view of Cupferman, would not seek to formulate an antimicrobial composition with a quaternary ammonium compound (*e.g.*, benzalkonium chloride), as recited by the claims. As such, because the combined teaching of the cited references fails to describe all the elements of the claimed invention (*i.e.*, a antimicrobial hydroalcoholic gel comprising two different zinc salts and synergistic amounts of octoxyglycerin and a quaternary ammonium compound), and because the skilled artisan would have no expectation that the various elements of the claimed

composition could be successfully combined together, Applicants respectfully request that the rejection be withdrawn.

**II. The Double Patenting rejection**

The Examiner has rejected claims 1-4 on the ground of nonstatutory obviousness-type double patenting as double-patenting over claims 1-2, 6, 24-25 and 29 of U.S. Patent No. 6,846,846 (“the ‘846 patent”). The Examiner contends that the ‘846 patent is directed to an antimicrobial composition comprising synergistic effective amounts of octoxyglycerin, a quaternary ammonium compound, and an antimicrobial compound selected from a biguanide, triclosan, phenoxyethanol, an iodine compound and parachlorometaxylenol. According to the Examiner, the claims of the instant application are not patentably distinct over the claims of the ‘846 patent.

Without conceding to the Examiner’s contentions, Applicants respectfully submit that the appropriate action will be taken (*e.g.*, through the submission of a Terminal Disclaimer), upon withdrawal of the rejections under 35 U.S.C. § 103(a).

**III. Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and the rejections withdrawn. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe no fee in addition to the fee associated with the supplemental Information disclosure Statement submitted herewith is due. However, if any other fees are required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit any overpayments made, to Deposit Account 02-4377.

Respectfully submitted,

BAKER BOTTS L.L.P.

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Date



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